

Message Text

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ORIGIN HEW-06

INFO OCT-02 EUR-12 EA-12 ISO-00 OES-07 /038 R

DRAFTED BY DHEW/FDA:JRWEINROTH,MD:VB
APPROVED BY OES/ENP/EN:WJWALSH II.
DHEW/PHS/OASH/OIH/RDFISCHER
EA/ANP - TJWADJA (INFO)
EUR/CE - SMKINGAMAN (INFO)
EUR/EE - KNBROWN (INFO)

-----018670 260337Z /62

P 252311Z JAN 78
FM SECSTATE WASHDC
TO AMEMBASSY CANBERRA PRIORITY
AMEMBASSY VIENNA PRIORITY
AMEMBASSY PRAGUE PRIORITY
AMEMBASSY PARIS PRIORITY
AMEMBASSY BONN PRIORITY
AMEMBASSY TOKYO PRIORITY
AMEMBASSY THE HAGUE PRIORITY
AMEMBASSY MOSCOW PRIORITY

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E.O. 11652: N/A

TAGS:OGEN, ETRD, EIND, TBIO, AS, AU, CZ, FR, GW, JA, NL, UR

SUBJECT: FDA ADVISORY-MALFUNCTIONING DIAGNOSTIC MEDICAL
DEVICE (RECALL R-004-8)

1. FDA ADVISES OF THE FOLLOWING:

PRODUCT INVOLVED: PHO/GAMMA LEM (LOW ENERGY MOBILE) SCINT-
ILLATION CAMERA; PRODUCT IS A PORTABLE DIAGNOSTIC INSTRU-
MENT USED TO DETECT TUMORS AND OTHER BODY ABNORMALITIES.

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PRODUCT IDENTIFICATION: "PHO/GAMMA LEM SCINTILLATION
CAMERA" IS SCREENED ONTO THE CONTROL PANEL. THE IDENTI-
FICATION PLATE IS LOCATED INSIDE THE DOOR BELOW THE
CONTROL PANEL. ON THE PLATE IS: "SEARLE RADIOGRAPHICS,
DES PLAINES, IL 60018 MODEL NO. 00EB6475.

SERIALNO. SEE BELOW

STOCK NO. 406475
LOT NO. (GROUPING MANUFACTURE NUMBER)
REVISION LEVEL
POWER REQUIREMENT 110 VOLTS.

MODEL NO. 00EB6475 WAS DISTRIBUTED OVERSEAS, AND THE
FOLLOWING SERIAL NUMBERS USED IN CONJUNCTION WITH IT:
33501/33512,P1-6,P1-15, AND P1-17.

MANUFACTURER/RECALLING FIRM: SEARLE RADIOGRAPHICS
DIVISION OF SEARLE DIAGNOSTICS
2000 NUCLEAR DRIVE
DES PLAINES, IL 60018

2.REASON FOR ADVISORY (RECALL RECOMMENDATION): UNEXPECTED
WEAR IN THE VERTICAL DRIVE MECHANISM CAUSES FAILURE OF THE
THREADS ON THE VERTICAL SUPPORT (ACME) NUT WHICH COULD
RESULT IN BODILY HARM. ON 10/3/77, WASHINGTON UNIVERSITY
HOSPITAL, ST. LOUIS MISSOURI NOTIFIED SEARLE THAT A 3 1/2
YEAR OLD FEMALE PATIENT UNDERGOING A BONE SCAN WAS CAUGHT
BETWEEN THE DETECTOR HEAD AND THE EXAMINATION CART AS THE
THREADS ON THE VERTICAL SUPPORT NUT FAILED, RESULTING IN A
FRACTURE OF THE SKULL AND POST SURGICAL DEHISCENCE OF THE
CRANIECTOMY SUTURE LINE. THE DETECTOR HEAD COULD NOT BE
POWERED UP AFTER THE ACCIDENT, NECESSITATING TILTING THE
DETECTOR HEAD TO REMOVE THE PATIENT. SEARLE EXAMINED THE
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DEFECTIVE DRIVE MECHANISM AND ALL RECALLED DRIVE MECHANISMS
AND FOUND THE FAILURE TO BE THE RESULT OF MISALIGNMENT
OF THE DRIVE MECHANISM AND INADEQUATE LUBRICATION OF THE
DRIVE MECHANISM. SEARLE INITIATED THE RECALL ON 10/4/77.
TELLING THEM OF THE POSSIBLE DRIVE MECHANISM DYSFUNCTION,
AND TO DISCONTINUE USE OF THE PHO/GAMMA LEM CAMERA UNTIL
EXAMINED BY A SEARLE SERVICE ENGINEER. A SEARLE SERVICE
ENGINEER EXAMINED EACH MACHINE WITHIN 48 HOURS OF THE
INITIAL NOTIFICATION, PLACED A WARNING LABEL READING "DO
NOT MOVE DETECTOR HEAD UP OR DOWN WHILE PATIENT IS UNDER
DETECTOR HEAD", AND GAVE THE CUSTOMERS A COPY OF THE
PRODUCT CORRECTIVE ACTION LETTER DATED 10/6/77. SEARLE
HAD PLANNED TO MAKE FIELD CORRECTIONS ON DEFECTIVE UNITS
FOUND, BUT DECIDED TO RECALL THE VERTICAL DRIVE ASSEMBLIES
TO SEARLE'S FACILITY FOR REPLACEMENT OF ALL WEARABLE PARTS
OF THE ASSEMBLIES. SEARLE NOTIFIED ALL OF THE DIRECT
ACCOUNTS ON 10/12/13/1977 INSTRUCTING THEM TO RETURN THE
ASSEMBLIES TO SEARLE FOR REPLACEMENT. UPON DETERMINING
THAT THE FAILURE WAS BASICALLY DUE TO INADEQUATE LUBRI-
CATION, SEARLE SENT LETTERS DATED 12/2/77 TO ALL DIRECT
ACCOUNTS INSTRUCTING THEM TO REMOVE THE WARNING LABEL OF
10/6/77 AND REPLACE IT WITH AN "IMPORTANT" LABEL WHICH

STATES "ONCE DAILY, RAISE DETECTOR HEAD TO FILL-HEIGHT THEN LOWER TO LOWEST POINT AND AGAIN TO FILL-HEIGHT TO ENSURE LUBRICATION OF DRIVE SYSTEM". SEARLE ALSO ENCLOSED REPLACEMENT PAGES FOR THE OPERATION MANUAL DESCRIBING THE SPECIFIC LUBRICATION INSTRUCTIONS. SEARLE'S PERMANENT CORRECTION COMPLETION IS TARGETED FOR MAY, 1978. ALL DRIVE ASSEMBLY UNITS WILL BE REPLACED WITH A REDUNDANT CATCH NUT SYSTEM WHICH WILL INCORPORATED A TORQUE LIMITING FEATURE THAT WILL STALL THE DRIVE MECHANISM IF THE ACME NUTS FAILS.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED INSTRUCTIONS FROM SEARLE RADIOGRAPHICS CONCERNING THE PROBLEMS ASSOCIATED WITH THIS UNCLASSIFIED

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MEDICAL DEVICE AND IF MACHINES HAVE BEEN MODIFIED AND NEW OPERATING MANUALS SUPPLIED. FOR THOSE MACHINES WHICH ARE DEMONSTRATION UNITS, IT IS RECOMMENDED THAT THE POST CONTACT THE RECIPIENT, G.D. SEARLE, NETHERLANDS, TO DETERMINE IF THESE MACHINES HAVE BEEN MODIFIED PRIOR TO FURTHER DEMONSTRATION USE. WITH RESPECT TO MACHINES WHICH WERE IN TRANSIT SERIAL NO. 33508 TO USSR (SOVIET UNION) AND 33511 TO CSSR (CZECHOSLOVAKIA), POSTS SHOULD CONTACT DISTRIBUTOR G.D. SEARLE, NETHERLANDS TO DETERMINE IF MACHINES HAVE BEEN MODIFIED AND NEW OPERATING MANUALS HAVE BEEN SUPPLIED. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS ADVISORY SHOULD BE DIRECTED TO THE FIRM, SEARLE RADIOGRAPHICS.

4. FOREIGN CONSIGNEES ARE AS FOLLOWS:

SERIAL NO.

PL-6: DR. L.M. DUGDALE, ALFRED HOSPITAL, VICTORIA, AUSTRALIA

PL-7: DR.KRAMER, INSTITUTE OF CARDIOLOGY, MOSCOW, U.S.S.R.

PL-15: PROF. RUDOLF/DR. SILBER, DUETSCHES HERZZENTRUM, DES FREISTAATES BAYERN, MUNICH, WEST GERMANY

PL-17: DR. M. IIO, JIKEI UNIVERSITY, TOKYO, JAPAN

33501: PROF. EMRICH/DR. SCHICH, DR. LUIG KLINIKEN, DER UNIVERSITAET, GOEETINGEN, WEST GERMANY

33502: PROF. EMRICH/DR. SCHICH, DR. LUIG KLINIKEN, UNCLASSIFIED

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DER UNIVERSITAET, GOEETINGEN, WEST GERMANY

33503: PROF. RAINDL/ENG. JOSKOWICZ/ DR. PACHINGER,
KARDIOLOGISCHE UNIVE., KLINIK, ALLGEMEINES,
KRANKENHAUS DER STADT, WIEN, VIENNA, AUSTRIA

33504: DEMONSTRATION MACHINE--G.D. SEARLE NETHERLANDS,
UTHTHOORN, NETHERLANDS

33505: DEMONSTRATION MACHINE--G.D. SEARLE NETHERLANDS,
UITHOORN, NETHERLANDS

33506: DR. DUCPASSOU, HSPTL, DU HAUT LEVEQUE, PESSAC,

33507: DAMAGED IN TRANSIT--RETURNED TO SEARLE

33508 IN TRANSIT IN U.S.S.R. WILL NOT BE INSTALLED
UNTIL UPGRADED. DISTRIBUTOR G.D. SEARLE,
NETHERLANDS.

33509 CONVERTED TO 33539 (MODEL NO. 00AA6475)--
DOMESTIC DISTRIBUTION

33510: DEMONSTRATION MACHINE--G.D. SEARLE NETHERLANDS,
UITHOORN, NETHERLANDS

33511: IN TRANSIT IN C.S.S.R. (CZECHOSLOVAKIA). WILL
NOT BE INSTALLED UNTIL UPGRADED. DISTRIBUTOR
G.D. SEARLE, NETHERLANDS

33512: DEMONSTRATION MACHINE--G.D. SEARLE NETHERLANDS,
UITHOORN, NETHERLANDS. VANCE

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 25 jan 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE020584
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH,MD:VB
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780038-0572
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780122/aaaaasra.tel
Line Count: 206
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 1d5009e0-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 15 feb 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3714257
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY-MALFUNCTIONING DIAGNOSTIC MEDICAL DEVICE (RECALL R-004-8)
TAGS: OGEN, ETRD, EIND, TBIO, AS, AU, CZ, FR, GE, JA, NL, UR
To: CANBERRA VIENNA MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/1d5009e0-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014